
Regulatory Framework for Food Health Claims

Q&A

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Carl Keen: One of the things that was stressed in the latest IOM¹ biomarker report is the suggestion that all of the food claims today should be at about the same level of a standard pharmaceutical. Miguel, you touched upon this. The cost of that may be prohibitive. Is it reasonable to ask that of the food industry or do we have to find some way to tweak it? Is there a light at the end of the tunnel?

Barbara Schneeman: FDA's goal with the biomarker report had been to identify a better process to develop validated biomarkers. For diseases for which we don't have valid biomarkers—many of the cancers for example—the only clinical studies that are possible to ascertain decreased risk are long term. With suitable biomarkers that are surrogate endpoints of disease, shorter-term studies are possible. So the recommendations were a little bit confusing based on what FDA had hoped to get out of that report, but we are gleaning, we are looking through it and hoping that the scientific community may be able to identify ways that they can take biomarkers that are currently in use and validate them as surrogate endpoints or develop new biomarkers that might be used in that capacity.

Roger Wasson (Wasson and Associates): You've talked about the regulations and about the rating systems and the labels, but I wondered if you would each go outside your own area and comment about advertising, because even some of the groups that you have regulated are able to come together and say something about "heart healthy" or omega-3 or something else, on the Web, in advertising and public relations—technically disconnected from the label itself—and advance a conversation on some of these issues that are quasi-claim making, but are not necessarily clearly regulated.

¹Institute of Medicine.

Joanne Lupton: Actually, I think it's the opposite right now. I'm actually surprised how the Federal Trade Commission, the FTC, is coming after people for advertising and Websites. If it's on the label and it's on the Website, it counts the same, and FDA can go after those individuals. That's coming under more scrutiny rather than less.

Schneeman: As Joanne mentioned, we have a guidance document on our Website pointing out when material on the Web can be considered labeling. For example, if a Website URL is provided on a food label then we can review anything on that Website as labeling. The most famous instance in the United States was the cherry juice case about cancer. We can also look at advertising as a way of understanding the manufacturer's intended use of the product. So, it's not that we are regulating the advertising, but if it gives us information in a situation in which we might need to take enforcement action, we can use it to help inform our process. As a segue from your question, FTC was instructed by Congress to convene a work group from CDC, FDA and USDA to develop a report on criteria for marketing foods to children and, in December of 2009, a workshop was held in Washington, DC, with a preliminary discussion of the criteria that the work group had been considering. FTC will publish a *Federal Register* notice with the proposed criteria, with the goal of receiving comment before it actually sends its report to Congress, which is due in July 2010. I know that this has been an area of interest in Europe as well. Children are a vulnerable group. Should we be taking more steps to manage what is marketed and promoted to children in terms of food choice?

Miguel da Silva: And, in the case of Europe, the claims regulation applies to all commercial communications, including Websites and advertising, as I said. For example, last year, I think it was the ASA, the Advertising Standards Authority, of the United Kingdom prohibited ads on television for some food companies because they were not complying with the claims regulation. So, that is already having an effect on advertising *per se* in the UK.

Rickey Yada (University of Guelph): We often talk about science-based policy. Should we be looking at policy-based science now?

Lupton: Actually there is definitely a role for both and what you heard from the panel here is how we use scientific evidence to support the development of a policy, specifically around claims. But, where we probably need the research to go in the other direction, keep in mind that the intent with nutrition labeling is to help consumers make better food choices, and research can be done to help us figure out whether we are achieving that goal. Are there ways that we should be improving our labeling? Certainly in the front-of-pack labeling arena, there is a lot of speculation that this is going to be a tool that helps consumers, particularly some consumer groups that aren't currently using Nutrition Facts. Research can help us understand behavior, so, as the policy evolves, you need research to understand the impact the policy is having.

da Silva: In Europe, we have clearer separation between the risk assessors and the risk managers. That's why, in my presentation, I explained that the European Food Safety Authority looks at the science, but it's really the Commission and the Member States that authorize or decline the claim. Now, they tend to follow EFSA advice, so if EFSA says that the claim is scientifically justified then the Commission and regulators will approve it. However, what we are seeing also is, in the case of nutrient profiles, EFSA gave an opinion on how profiles could be established, but now it's pure politics. No science is involved.

Amanda Martin (University of Minnesota): Even if you ban claims, you're not banning the food. Will it actually affect consumer choice? By taking away the "probiotic" claim will yogurt consumption rates go down?

da Silva: Yes, that is a problem. For a functional food, if they cannot make a claim, who will pay more to buy it? And that's particularly the case for antioxidants, for probiotics and for all food supplements. If you have a pill, but the label doesn't tell you what it does for you, then why would you buy it? So, it really has a serious impact. Of course, even if a claim is prohibited, your product can remain on the market, but, if you have developed it as a functional food delivering a health benefit, you will want to communicate that to the consumer. When claims for probiotics were being rejected, Dannon withdrew their dossier on Activia, so as not to have a public rejection on their dossier. They have stopped their claims, but are keeping the products on supermarket shelves because people, having been "educated," are familiar with the media messages. However, I wonder what will be the situation in a number of years, because to educate people you need to educate constantly as the consumer population evolves.

Schneeman: You raised an interesting point and it can play out in different ways. First of all, yogurt can be part of a healthful diet. If you are interested in consuming dairy products, that is certainly one way to do it. It's not surprising that consumers tend to think positive of a product like that. A company that chooses to go down that path has to weigh the risks to them. Because, on the one hand, they do gain a halo if it looks like their product has a health benefit. But then, having a negative message come out about that product could tarnish that halo. If consumers already believe it and let's say it's a placebo effect, then the tarnish may not impact them, but, in some cases, it can have a much more negative effect: why would I trust a company that has said something not supported by the science? It gets complicated in terms of the messaging and how consumers perceive it.